EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

****

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION — MDL No. 2875

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THIS DOCUMENT APPLIES TO ALL CASES — HON ROBERT B. KUGLER

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- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

Videotaped Deposition of PUNAM ANAND KELLER, Ph.D., commencing at 9:19 a.m. Eastern, on the 10th of March, 2022, at the offices of Duane Morris, 100 High Street, Boston, Massachusetts, before Maureen O'Connor Pollard, Registered Diplomate Reporter, Realtime Systems Administrator, Certified Shorthand Reporter.

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None.

P R O C E E D I N G S

THE VIDEOGRAPHER: We are now on the record. My name is Alex Jandrow, I'm a videographer for Golkow Litigation Services.

Today's date is March 10, 2022, and the time is 9:19 a.m.

This video deposition is being held in Duane Morris LLP of Boston Massachusetts in the matter of Valsartan, Losartan, and Irbesartan Products Liability Litigation, MDL Number 2875, for the United States District Court, District of New Jersey.

The deponent is Punam Keller, MD.

And the court reporter is Maureen O'Connor Pollard.

Counsel will now introduce themselves for the record.

MR. DAVIS: John Davis and Ruben Honik for the plaintiffs.

MR. GOLDBERG: Seth Goldberg on behalf of the ZHP defendants and defendants.

MR. SMOLIJ: Alek Smolij on behalf of the ZHP defendants.

MS. ANDRAS: Tiffany Andras on behalf of Teva and Actavis Pharmaceuticals.

MR. DAVIS: Good morning, Dr. Keller. How are you today?

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PUNAM ANAND KELLER, Ph.D., having been duly identified and sworn, was examined and testified as follows:

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THE WITNESS: And the first thing I want to do is, it's not MD, it's Ph.D.

EXAMINATION

BY MR. DAVIS:

Q. Okay. Let me try that again.

Good morning, Dr. Keller. How are you this morning?

A. Good. How are you?

opinions and the basis and reasons for them?

A. Yes.

Q. Okay. You didn't do any kind of survey or empirical study as part of your assignment in this case, did you?

A. No, because I felt that there was evidence from consumers as well as literature from consumers that were sufficient to support my opinions.

Q. We'll get into that a little bit later.

But your answer is no, you did not do a survey or any kind of empirical study as part of your assignment in this case?

A. Yes.

Q. Okay. Have you been asked to at some point in the future?

A. No.

Q. I think you said earlier that you've done some consumer messaging in the field of healthcare, is that correct?

A. Yes.

Q. Okay. Can you describe that

have an opinion.

Q. Well, the question is do you know.

A. No.

Q. Are you familiar with the fact that generic pharmaceutical manufacturers do not routinely engage in promotional activities for their drugs?

A. I do not know.

Q. When I refer to FDA-approved labeling, do you know what that means?

A. Could you be more specific?

Q. Sure.

Do you know what an FDA-approved label is?

A. No.

Q. Have you looked at any FDA-approved labeling for any of the generic valsartan products at issue in this case?

A. I have looked at some labels of valsartan. I do not know if they are FDA-approved or not.

Q. In general terms, the labels that you looked at, what kind of information

decision rule, do you not?

A. I do not say that.

Q. Take a look at paragraph 9 of your report, first bullet point. You say in the middle of that bullet point, "In doing so, Dr. Conti's analysis implicitly relies on a uniform noncompensatory decision-rule for calculating damages."

Do you see that?

A. Yes.

Q. So you are saying that she's applying a uniform noncompensatory decision rule, do you not?

A. You forgot a critical word. No, I did not say that, I said she is implicitly applying.

Q. How is that different from her applying, which is my question?

A. The different between an explicit and an implicit application. She does not mention a noncompensatory decision rule, but her assertions are consistent with a noncompensatory decision rule, which is why I said she implicitly applies a

noncompensatory decision rule.

Q. Okay. Thank you for that. That was going to be my next question, is Dr. Conti never uses that term in her report, does she?

A. No.

Q. Thank you.

That's a term -- compensatory decision rules, noncompensatory decision rules, those are terms that are borne out of the field of sort of behavioral science, right? Consumer behavior, consumer psychology, your field of expertise, correct?

A. As I mentioned in my testimony earlier, the foundation for some of this work on compensatory/noncompensatory decision rules came from economists, and I mentioned several, Simon, Tversky, Kahneman, amongst others.

Simon actually was the first one that came up, from what I know, or is at least given credit for the first noncompensatory rule satisfying. This is Herbert Simon, he's an economist.

Q. This is behavioral economics, correct?

A. At that time it was not defined as such, but he's an economist, and now it is commonly adopted in behavioral economics as well.

Q. Let's go to paragraphs 21 through 28 of your report. And this is where you set forth some discussion and definitions of what you mean by compensatory decision rules and noncompensatory decision rules, is that correct?

A. Yes.

Q. For example, in paragraph 22 you state that "The compensatory decision-rule involves physicians and consumers placing a higher value of one drug feature to compensate for a lesser value of another feature," correct?

A. Yes.

Q. There's an assumption there, is there not, that the information regarding those features is available for them to actually weigh, correct?

A. No.

MR. GOLDBERG: Objection.

Asked and answered.

BY MR. DAVIS:

Q. In your report on paragraph 38 you mention that Accutane "has a number of potentially serious side effects, including: eye irritation; skin infection; bone tenderness; vision loss; birth defects (in pregnant women); skin inflammation."

Do you see that?

A. Yes.

Q. Where did you get that information from?

A. Footnote 62, and it's in Appendix B of my report.

Q. Okay. So that is -- that appears to be the label, so you did --

A. I didn't know that's what the label was. Thank you.

Q. Yes. So this is the label. So you have looked at this?

A. Yes.

Q. And that's how you pulled out

for example, these potential side effects, was from looking at what's been marked as Exhibit 5, correct?

A. Sorry, can you repeat the question? What has been -- sorry, can you ask the question again?

Q. Sure.

The way you came to understand that Accutane carries the risk of these side effects that you discuss in paragraph 38 is because, as you cite in footnote 62, you actually went and looked at the label for the drug, correct?

A. That's right.

Q. Okay. And that's where those side effects were disclosed?

A. I'm sure -- there may be more, but that's where the ones I've listed were disclosed, yes.

Q. So essentially what happened here is the FDA approved Accutane, correct? The FDA granted approval for Accutane to be marketed to Roche, which was the brand company as you see there.

Do you understand that?

A. I take your word for it.

Q. And they approved Accutane despite the drug carrying these disclosed side effects, correct?

A. I'll take your word for it.

Q. And left it up to physicians and consumers to weigh the costs and benefits of taking the medicine with those -- with the knowledge of those disclosed side effects in the label, right?

A. Yes.

Q. Okay. Let me ask you, how do you think users of --

A. Should I put this away?

Q. Sure, if you want to.

How do you think users of generic Accutane manufactured by Ranbaxy weighed the fact that that generic Accutane was contaminated?

A. Could you please repeat the question?

Q. Sure.

Are you familiar with a company

called Ranbaxy?

A. No.

Q. Okay. Let me mark something else for you.

MR. DAVIS: I'm handing Exhibit 6 to the reporter to be marked.

(Whereupon, Keller Exhibit Number 6 was marked for identification.)

BY MR. DAVIS:

Q. Okay. I'm handing you a -- Exhibit 6, for the record, is a US Department of Justice press release titled "Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA."

Do you see that?

A. I see it.

Q. That's dated May 13, 2013?

A. I see.

Q. Okay. So, in fact, if you -- just to orient you, if you go back to

Exhibit 5 just for a moment, which is the Roche label for Accutane, do you see what the generic name for that drug is?

A. Exhibit -- where? It's a big document.

Q. Well, actually it's in your report at paragraph 38, "As an example, Accutane, or isotretinoin."

A. Yes.

Q. Do you know that Accutane's generic name is isotretinoin?

A. Yes.

Q. Okay. I'm going to direct your attention to page 2 of Exhibit 6, which is this DOJ announcement.

A. Okay.

Q. And you'll see in the second paragraph on that page, "Ranbaxy USA admitted to introducing into interstate commerce certain batches of adulterated drugs that were produced at Paonta Sahib in 2005 and '6, including Sotret, gabapentin, and ciprofloxacin."

And then it says, "Sotret is

Ranbaxy's branded generic form of isotretinoin," which is Accutane, correct?

A. Is the generic form.

Q. Right.

A. Yes.

Q. So do you see there that Ranbaxy admitted that in 2005 and '6 that they distributed adulterated isotretinoin?

A. According to this statement, yes.

Q. Okay. So my question is, how do you think consumers of Ranbaxy's Sotret or isotretinoin manufactured by them who got that drug in 2005 and 2006 were able to weigh at the moment they went to the pharmacy and got it the fact that it was adulterated?

MR. GOLDBERG: Objection to form.

I think it would be fair to allow the witness to review the document, given the question.

BY MR. DAVIS:

Q. You don't need to review the document to answer the question. I'm asking

it's going to take longer we'll go off the record. But we don't go off the record automatically just because a document is presented. That's how it goes.

BY MR. DAVIS:

Q. Feel free to give the document a cursory review.

A. I'm sorry, I'm going to undertake my task so that I can answer your question to the best of my ability.

Q. Sure. Okay.

A. Thank you.

Q. Review the document.

A. Thank you.

(Witness reviewing document.)

A. Thank you.

Q. Sure. So let's start with the portion of the document that I called out to you.

You agree that Ranbaxy admitted to distributing in 2005 and 2006 certain batches of adulterated isotretinoin, which is generic Accutane, correct?

A. Yes.

Q. Okay. So my question is, how can consumers who purchased those drugs in 2005 and '6 have weighed the fact that they were adulterated at the time that they purchased them?

A. You are making an assumption that consumers uniformly would have wanted to weigh that fact.

Q. No, that's not my question, and you're not answering my question.

My question is, how could they have weighed that information when it wasn't disclosed to them?

A. But the assumption is that they would even want to. So if I don't want to, the issue of how I could is irrelevant.

Q. Well, you're taking it -- you're taking my question and you're answering a different question.

A. I see.

Q. My question is, how can consumers who purchased adulterated Ranbaxy isotretinoin in 2005 and 2006 that was

adulterated, how could they have weighed the fact that it was adulterated? If they wanted to weigh that fact, how could they have weighed that fact that it was adulterated? They couldn't, right?

A. Again, I'll explain why I'm having a hard time answering that question directly.

Based on my understanding of consumer behavior, there are consumers who think drugs are adulterated when they're not and consider that. And the example that I give in my report was on -- because we were talking about COVID vaccine earlier, about bleach, and I cited a supporting document, you know, something from the CDC on the percentage of people that were using bleach because they thought that was more efficacious for them or safer or whatever set of reasons they had that I'm unsure of than the COVID-19 vaccine.

So I don't -- I said this earlier, I don't think that consumers need to get specific information in order for them to

include features, whether they're benefits or costs or both in some cases, in order to make a determination of how they impact the value that they are assessing.

Q. You don't think consumers are entitled -- you don't think these Ranbaxy isotretinoin consumers were entitled to know that the drug they got was adulterated? Is that what you're saying?

A. No, I did not say that. I actually don't know what you mean by "entitled."

Q. You don't think it would have been right for them to know that the drug they were getting was adulterated?

A. There are some consumers who would say, It is my right to know, and there are others who would say, I don't care.

There is a range of consumer behavior, and I don't think that you can uniformly assume any consumer would be exactly the same in this context of they would feel that they have the right to know.

Q. But you're not answering my

question. You're answering a different question, which is how they might have weighed that information or not have weighed that information.

My question is, it wasn't disclosed to them, so even if they wanted to weigh it they couldn't have, right? Even if they would have considered that in their decision-making, they couldn't have, right, because it wasn't disclosed to them. Would you agree with that?

A. So you're saying make the assumption that people -- that there were people who wanted to know, and then -- you're asking me to make a lot of assumptions.

Q. Well, I don't think it's a big assumption to assume that people would want to know that their drug was contaminated.

A. Some will and some will not, and that's what I said.

Q. Assume it for me, Dr. Keller, assume that there were patients of Ranbaxy's Sotret who would have wanted to know that information.

A. Okay.

Q. But they didn't know that information at the time they purchased the drug, right?

A. Correct.

Q. Okay. How could they have weighed that information when it wasn't disclosed to them? They couldn't have, right? They could not have weighed that information, correct?

A. They could not have weighed the specific information, but they could have weighed related information.

Q. What do you mean by "related information"?

A. You know, there are consumers out there who believe that pure drugs is an oxymoron, and that -- you know, and as I state in my report in Section IV, I think it was IV.B, which is what we were referring to earlier, there are some consumers who learn over time that things that they thought were safe were not safe, and things that they thought may have not been safe have reentered

don't think consumers of pharmaceuticals dispensed in the US should be entitled to a belief or an expectation that those drugs are dispensed to them as described and approved by the FDA?

A. Again, I don't believe that is the case for all consumers. I think many consumers don't think about whether the drug is approved or not approved, or who approves it or doesn't approve it.

And I'm going to break one of my own rules and give you an example where if I was taking a drug, and it could be this one that you have as an example, and I thought it was working brilliantly for me, I might not want to know that the drug -- I mean, sorry, I can say drug, yeah -- that the drug was adulterated because I would like to continue taking the drug without any trepidation.

Q. You might not want to know?

A. I might not want to know.

Q. Well, what if -- I mean, we're talking about just one manufacturer's version of generic Accutane, you wouldn't want to

know that so you could just take another manufacturer's version of generic Accutane that wasn't adulterated?

A. It's a hypothetical, so I'm giving you a hypothetical back, and that is, if I like this one that I'm taking and it's worked for me -- and back to my framework that I talk about in the model, and I'll use MICI this time, which is, depending on the message that I got -- and I can give you examples, depending on -- I'm focusing on the individual differences, that if I've tried other acne medicines and they haven't worked for me, and then I find one that I really like and it seems to work for me, and then there is this information out there, I'm saying that there are some consumers in those situations that might not want to know or not care about this information about the adulteration from this specific batch because they don't want to switch, they don't want to consider any alternative products.

Q. Do you understand that the point of our generic drug system is that all

the generics are supposed to work in the same way to each other and to the brand?

MR. GOLDBERG: Objection.

BY MR. DAVIS:

Q. Do you understand that?

MR. GOLDBERG: Objection to form. Asked and answered.

A. I am not an expert on how generics are supposed to work, and I will not give you an opinion on that.

BY MR. DAVIS:

Q. Let's back up for a second.

You talk a lot about this choice exercise that consumers make in the healthcare context, right?

A. Which context are you speaking? We were talking about how a consumer might value the drug that they have, so when you say "choice exercise," I'm trying to understand the context.

Q. Sure.

Your whole report is about healthcare decision-making, right? And that involves a choice, right?

A. I would say that that's a bit of a mischaracterization. The bulk of my report is focused on how consumers would assess the value or worth of a drug to them.

Q. Okay. And once they make that assessment, at what point is the decision finalized for them?

A. Lots of cases, never. In some cases, they try one, they never switch. That varies by consumer.

Q. Well, the choice is culminated when they go buy the drug, right? They're acting, would you agree --

A. No, no.

Q. Would you agree that a consumer, when they go fill a prescription, they're acting on a choice that they've made, correct? They may -- I hear what you're saying, they may reevaluate that choice in the future, but they're acting on a choice that they made prior to that, because they had to -- I mean, it's just common sense, you go fill a prescription, you're doing an act, right?

A. As I mentioned to you earlier, the consumer value is defined as a comparison of benefits and costs, and the price they pay or the act of actually exchanging a product for money is only one aspect of the cost.

Q. It's an action, though, that a consumer is taking, correct?

A. It's one of several.

Q. As a result of the decision and choice analysis that they went through prior to engaging in that act, right?

A. I take objection to that. As I explain in my report, and this is in Section IV.B of my report, consumers use a variety of different methods to make those choices. Some of them are noncompensatory or reflexive, they haven't thought about anything, they've just gone and done it spontaneous, others -- there's a range -- others will spend a lot of time and think about the plusses and minuses. There's a range.

Q. I'm not going into the qualitative aspect of that choice. All I'm

saying is that in order to act, which is to go fill the prescription at the pharmacy, some level of choice had to be made to go do that. We're not talking about zombies here who are just like, you know, going to the pharmacy, this is a choice that humans make to go fill a prescription, is it not?

A. I would say some will go fill and some will not. And again, as is explained in my report, many consumers do not fill their prescriptions, and many consumers who fill their prescriptions do not take their drugs. So those are also actions.

Q. So with this Sotret example, which consumers affirmatively made the choice to go get adulterated Sotret from Ranbaxy?

A. I have no idea.

Q. None, right?

A. Well, no, that is -- I have no information on that. I can't tell you that.

Q. If you don't know -- if they didn't know about it, how could they affirmatively go choose that at the time? They can't, right?

Q. No, I was resetting our --
A. I'm sorry. Okay.
Q. -- context here.
Have you examined in any detail how the fact of adulteration in this case, for example, affects a company's ability to supply their drugs into the US?
A. I need a clarification.
Q. Sure.
A. In this case are we talking about the Ranbaxy case, or are we talking about the VCD case, or some other case?
Q. I'm just talking generally about pharmaceutical prescription drugs.
A. Okay.
Q. Did you as part of this assignment, or not as part of this assignment, just generally, have you ever studied how the fact of a prescription drug's adulteration affects its ability to be distributed, marketed, sold, dispensed in the United States?
MR. GOLDBERG: Objection. Ambiguous and compound.

A. I am not an expert on many of the things that were raised, and I'm not going to give an opinion.

BY MR. DAVIS:

Q. So you haven't looked into how the fact of adulteration might affect the supply of a drug in the US?

A. Not prior to this case.

Q. Did you in this case?

A. I reviewed Dr. Conti's report, so yes.

Q. Okay. I'm asking not did you review Dr. Conti's report. I'm asking if you did any independent analysis of your own how the fact of adulteration under the law might affect the supply or the ability of a manufacturer to supply its drug product in the United States market?

A. No. I am a consumer behavior expert. I have no opinion on drug supply for the example you've given.

MR. DAVIS: I'm going to mark Exhibit 7.

///

(Whereupon, Keller Exhibit Number 7 was marked for identification.)

BY MR. DAVIS:

Q. I understand you're not a lawyer, Dr. Keller. What I'm showing --

MS. ANDRAS: Can you please identify it with specificity on the record?

MR. DAVIS: Sure. For the record, this is Exhibit 7, which is 21 USC 331, part of the US Code entitled "Prohibited Acts."

BY MR. DAVIS:

Q. Do you see that?

A. Yes.

Q. Do you have familiarity with what the US Code is?

A. No.

Q. Do you understand that that's federal law enacted by congress, signed by the President?

MR. GOLDBERG: Objection to form. Foundation.

A. I did not know that. I'm not an expert on the law.

BY MR. DAVIS:

Q. Okay. I'm granting you that.

It says there that, "The following acts and the causing thereof are prohibited." And then it says, "(a) The introduction or delivery" into -- sorry. "The introduction or delivery for introduction into interstate commerce of any," and it lists several things, including drugs, that are adulterated or misbranded.

Do you see that?

A. Yes.

Q. Okay. And then (c) says, "The receipt in interstate commerce of any" of the same categories, including drugs, that are adulterated or misbranded, and the delivery or preferred delivery thereof for pay or otherwise.

Do you see that?

A. I do.

Q. Okay. Were you aware -- your testimony is you're not aware of these

prohibitions under federal law, are you?

A. Correct.

Q. Okay. Thank you.

MR. GOLDBERG: Are you done with this one?

MR. DAVIS: For the moment, yes.

BY MR. DAVIS:

Q. Do you have any opinion about, or -- let me rephrase it.

Do you have any understanding about whether the at-issue VCDs in this case were deemed to be adulterated or misbranded under the law?

A. I don't have an opinion.

Q. Okay. You don't have any understanding, correct?

A. That's not what you asked. You asked if I had an opinion. So could you reask the question?

Q. Sure.

MR. HONIK: I'd like Maureen to read it exactly as John posed.

THE WITNESS: Thank you.

(Whereupon, the reporter read back the question:

QUESTION: Do you have any understanding about whether the at-issue VCDs in this case were deemed to be adulterated or misbranded under the law?)

MR. HONIK: Not opinion.

A. I apologize.

Could you read that again?

(Whereupon, the reporter read back the question:

QUESTION: Do you have any understanding about whether the at-issue VCDs in this case were deemed to be adulterated or misbranded under the law?)

A. I am not a lawyer. I do not -- I am not going to offer any opinion on that.

BY MR. DAVIS:

Q. Okay. And the question was, you don't have any understanding of whether they were or not, correct?

A. Please explain what you mean by

"understanding."

Q. So my question was, do you have any understanding of whether the at-issue VCDs in this case were deemed to be adulterated or misbranded under the law?

A. I will answer to the best of my ability. I have read the -- as you can see in Appendix B of my report, I have read a couple of legal documents that explain that some of the at-issue VCDs were found to be adulterated and unbranded under the law.

Q. Okay. But you're not sure how many, right? You said "some." You're not sure whether it's some or all of them, are you?

A. I am -- my understanding, which is what you asked, is that of the VCDs that were voluntarily recalled by the manufacturers, some of them, not all of them, were adulterated or unbranded.

Q. You're not sure how many that is, though?

A. No.

Q. Okay. And you didn't do any

independent analysis of whether that's true or not true, right?

A. Correct.

Q. Okay. Do you have any understanding of whether there are valsartan-containing drugs out there that don't have and never had NDMA and NDEA in them?

A. I am not an expert. I will qualify that some of the material that I have in my supporting documents suggested -- indicated to me that there were levels of these two impurities that you just mentioned, but I am assuming they were acceptable levels.

Q. So my -- that's not my question, though. My question -- and I'll reask it just to make sure we're clear, my question is, do you have any understanding of whether there were not at-issue VCDs manufactured by entities other than the defendants in this case that did not have any NDEA or NDMA in them?

A. I have no information on them.

Q. You have no information on that.

Didn't look at it?

A. No.

Q. Didn't investigate it?

A. No. Not part of my task.

Q. Do you have any understanding of whether NDMA or NDEA are supposed to be in valsartan drugs?

A. I'm not an expert on the formulation of these drugs. I have no opinion.

Q. Okay. So you don't know whether these two substances are supposed to or not supposed to be in valsartan drugs?

A. I am not an expert. I cannot comment as to the presence, absence, or extent to which these are or are not necessary for these drugs.

Q. Well, the drugs were recalled, as you said, right?

A. (Nodding in the affirmative).

Q. Doesn't that indicate to you that they weren't supposed to be in there?

A. My caveat is when you say they're not supposed to be there, my understanding is that they are there, it's just not they're not supposed to be there above certain levels, and that's what I'm qualifying.

Q. But you don't know whether they're supposed to be there at all or not, correct?

MR. GOLDBERG: Objection to form. Foundation.

A. No.

BY MR. DAVIS:

Q. Did you look at a valsartan label like you looked at the Accutane label?

A. I already testified that I looked at valsartan product labels.

Q. Can you point me -- it may be in there, I just want you to point me to where in your materials considered that would be.

A. I can show you from my report, but I don't have the binder of all the -- and actually there's maybe six on a page, they're

visuals, in case you have those materials and you're trying to look for them, but I can help.

(Witness reviewing document.)

A. I'm -- I wish I had my materials in front of me, but I'm going to -- I don't want to guess. It could be in the drugs.com or the MedlinePlus. I'm picturing the page in front of me, and they're pictures of multiple labels with on the left side the name, and on the right side the drug manufacturer and the place of manufacture. That's what I'm picturing.

Q. Okay. You say -- flip to page 30 of your report, if you don't mind, Exhibit 1.

A. Of course.

Q. The title of that section is "Real-world Evidence Indicates that the At-Issue VCDs Held Value," correct?

A. Yes.

Q. Okay. Did you look at any sales data of -- sorry.

Did you look at any sales data

of the actual sales of these drugs after the recalls were announced?

A. Only information that was part of Dr. Conti's report, not otherwise.

Q. So do you know what happened to sales of these products after the recalls?

A. I don't recall.

Q. Sorry, give me a few moments here. I should have two copies of all this somewhere, but I don't. I'm just going to mark one, it's big enough for, I think, you to see it.

MR. DAVIS: This is being marked as Exhibit 8, let's start with that.

(Whereupon, Keller Exhibit Number 8 was marked for identification.)

BY MR. DAVIS:

Q. Let me represent to you that what I'm showing you there is the monthly prescription data for --

A. Should I put the -- my report away?

A. Okay. Then yes.

MR. GOLDBERG: Objection to form.

BY MR. DAVIS:

Q. Do you understand why for ZHP the monthly sales dropped to zero?

A. I don't have that information.

Q. Did you come to any understanding or investigate whether similar to Ranbaxy, ZHP was barred from importing prescription drug products to the US?

A. I just want to make sure, exporting, that ZHP was barred from -- we barred them from imports of their product, right?

Q. Yes. ZHP products were made illegal to sell in the US, correct?

A. Yes.

MR. GOLDBERG: Objection to form.

BY MR. DAVIS:

Q. And subject to seizure by federal agents if they were imported or attempted to be distributed?

A. I am not an expert on this process. I cannot form an opinion.

Q. Well, you sort of do form an opinion, though. If you look at paragraph 71 of your report, you have a hypothetical supply-demand curve, do you not?

A. Excuse me, I need to get there. Could you ask that question again?

Q. Sure.

You said you don't have an opinion one way or the other on whether ZHP was barred from importing or selling its products in the US. Am I right about that?

A. I'm not sure, that may have been before your last question, I don't recall that as your last question, so I'm trying to be accurate.

MR. DAVIS: Could you read that last question? Sorry.

(Whereupon, the reporter read back the following:

QUESTION: And subject to seizure by federal agents if they were

imported or attempted to be distributed?

THE WITNESS: I am not an expert on this process. I cannot form an opinion.

QUESTION: Well, you sort of do form an opinion, though. If you look at paragraph 71 of your report, you have a hypothetical supply-demand curve, do you not.

THE WITNESS: Excuse me, I need to get there.

Could you ask that question again?

QUESTION: Sure.

You said you don't have an opinion one way or the other on whether ZHP was barred from importing or selling its products in the US. Am I right about that?)

BY MR. DAVIS:

Q. So let me -- I'll withdraw the last question.

You do at paragraph 71 on

page 43, the next page over, supply a hypothetical supply-demand curve, do you not?

A. Several.

Q. Well --

A. Several demand curves, and therefore --

Q. You have several demand curves, but you have one supply, correct?

A. Yes, so a combination would be several supply-demand curves.

Q. Right. But with one supply line, correct?

A. Yes.

Q. And this is hypothetical, right? This is a hypothetical supply-demand curve, is it not?

A. Well, it is a figure, and the changes or the alternatives of the demand curve that I'm sharing with you here reflect my argument that consumers would have different assessments of what the drug would be -- what the at-issue VCD would be to them, and based on the compensatory/noncompensatory decision rules and MICI.

And some consumers would say, I don't want any of this product, it is not worth anything to me, all the way to the other end of the continuum where you have some consumers who would say, I'm consuming these impurities in multiple forms and it's of no consequence to me, and everything in between.

That's what these alternative demand curves, or multiple demand curves are meant to represent.

So when you ask the question, you know, are they hypothetical demand curves, yes, they are, as that they're not based on data, nor is the supply curve, by the way, based on data, they're just representing how my frameworks and opinions would translate into alternative demand curves.

Q. Okay. And that was -- I think you've answered my next question, which is, this is not informed by any look at data, is it? These are hypothetical scenarios you're putting forward, right?

A. Yes.

Q. And in fact, your supply curve is just inconsistent with the facts if you accept, for example, the ZHP graph as actually representing the sales situation, correct?

A. It is incorrect, because the example that I'm giving you in my report is that one can retrospectively go to those consumers -- because there was supply, they were supplied the product. I mean, I'm not a lawyer, but how do you have a recall if there's -- no product was given? How do you make, what, ZHP or any manufacturer say they committed fraud because they sold something if they didn't sell anything. So if there's no supply, how is it possible if someone sells something that there's no supply.

So I'm just saying that this to me is not relevant -- sorry, your -- what exhibit is this?

Q. This is Exhibit 8.

A. Sorry. Oh, I see that.

Exhibit 8 does not help inform

I'm relying on my frameworks, depending on how that message was communicated, if you say carcinogen-laced the way you said it versus a valsartan that may contain impurities, the individual's -- I'm using MICI factors -- the individual's status, so if they were happy with their valsartan and had -- as I shared in my report in Section IV.E, they were happy with their valsartan, they had serious health issues, they may have even tried alternative medications and felt that the valsartan was the best at controlling their hypertension, and contextual factors, how much their relationship with their doctor and their ability or inability to have a healthy lifestyle, all of those factors would have an impact on what they thought the drug was worth.

BY MR. DAVIS:

Q. Okay. But you're not answering my question.

My question is, if there's no supply after the recall, as you can see from the sales data, even if a consumer -- like

let's just assume that there is a consumer who does want ZHP valsartan after the recall and wants to go get a new prescription of it from their doctor, the result is just like it was with Fen-Phen, they can't get it, right?

A. I'm assuming that is the case, yes.

Q. And they would end up, therefore, paying no money for it, correct?

A. Yes.

Q. Okay. Thank you.

And there would be no intersection of -- sorry, showing you my screen, you've got it right there.

A. Yes.

Q. There would be no intersection of supply and demand in that very specific situation I just asked you about, correct?

A. Correct.

Q. Okay. Thank you.

A. Should I put these away?

Q. Sure.

A. Okay.

MR. DAVIS: I'm marking

Exhibit 9.

(Whereupon, Keller Exhibit Number 9 was marked for identification.)

BY MR. DAVIS:

Q. This is a -- can you identify this document for me?

A. No.

Q. I'll represent to you that it's a valsartan -- I'll represent to you that it's a valsartan label, which may or may not -- I think, we looked at your materials considered.

Is this a document you recall seeing ever?

A. No.

Q. Okay. I'll represent to you -- but, you know, you're free to look, but I'll represent to you that there's no mention of nitrosamines, NDMA, NDEA, anywhere in this label.

Are you willing to accept that, or do you want to take a look?

A. I actually don't have any idea

what is in this label period, so I don't know how to understand the absence of the two impurities you just mentioned.

Q. Well, I'm not asking you yet to understand the absence of them. I'm just asking you if you see any reference to them in that document.

A. I cannot do that. You're asking if there's any reference, and I don't know if there's any reference without having a chance to review the document.

Q. Okay. So you're not willing to take my word for it that they're not in there? You're willing to look. Why don't you take a look, that's fine.

Do you want to look at -- and I can direct your attention, for example, to make this go a little faster, okay, if you don't mind, go to the very last page.

Do you see that last question there, "What are the ingredients in Diovan?"

A. I do.

Q. Okay. Do you see any reference to NDEA, NDMA?

A. I am not a chemist. I don't know the different forms and labels. Those drugs may be represented some other way. I cannot answer the question.

Q. Would you agree with me -- let's start with just a very general proposition.

Would you agree with me that a manufacturer of valsartan when they distribute it into the US market, by calling it valsartan and by distributing this label with it, they're conveying some kind of message to the people that will interact with it, namely physicians and consumers, correct?

MR. GOLDBERG: Objection to form. Foundation.

A. Please be more specific.

BY MR. DAVIS:

Q. Do you think that by -- when a manufacturer of valsartan distributes valsartan in the US market, by calling it valsartan, are they conveying a message that it's valsartan? It's a pretty general proposition, right?

multiple messages? It's a pretty simple question.

A. I cannot answer that question. I mean, if you're just saying is there communication about valsartan in here? I would say yes. For me, a message has a different meaning, and I would need to read the document to understand what the message -- multiple messages might be.

Q. Okay. Let's go back to your report for a moment, and again that section E that's titled Real-world evidence indicates that the at-issue VCDs held value.

A. Yes.

Q. And I understand you have -- you know, and I'm going to try and short-circuit a long back and forth here by stating that I understand that you have quite a few sources of general applicability here to support what you're saying amounts to real-world evidence of value.

My question very specifically here is, what evidence from this fact situation and case specifically, what

valsartan-specific evidence do you have that is real-world evidence that indicates that the VCDs at issue had value?

A. I have evidence from the individual depositions from the plaintiffs, and I have quoted some of them, who said that the at-issue VCDs provided them with therapeutic benefit.

I want to qualify, this is a small subset of depositions. I know that there were probably thousands if not tens of thousands consumers who took valsartan and this is a small group. But this is one source of evidence that consumers who took the at-issue valsartan said that -- some of them, not all of them -- that it helped them with controlling their blood pressure, that they had fewer side effects such as light-headedness and dizziness and nausea, and that they did not suffer any extreme emotional consequences to the point of actually seeking professional help. So those are just some examples of value from the real-world evidence.

I also -- the other sources of value also come from information in the public press as well as in some of the depositions, in the individual plaintiff depositions, where physicians are either publicly recommended, for example, I believe Dr. Neeson, to AARP group members that, you know, they should not stop taking the at-issue VCDs on their own without talking to their physicians because it is more important to control their blood pressure, and they could face very serious consequences, health consequences if they stopped, and that it would be -- the trade-off would be -- even if there were any problems in the short or the long-term with regard to any of the potential cancers, which again would vary across individuals, that the immediate serious health consequence of stopping their at-issue VCDs would be serious.

So the sources, just to sum, are the plaintiff depositions as well as -- as well as physicians. This includes cardiologists who shared that the at-issue

VCDs held value.

Q. Anything else, or those two?

A. I will also add -- thank you for asking -- the FDA also mentioned that consumers or patients who were taking the at-issue VCDs should not stop taking the VCDs, thereby indicating that they held value, unless, you know, an alternative was available to them. So that is also a source.

So I appreciate your giving me a chance.

Q. Sure.

So you've identified those three things. Is that everything?

A. To the best of my recall.

Q. Sure. Okay. Well, let's, I guess, take them somewhat in order.

You concede, you know, for the first point, which is the plaintiff depositions, you do concede at paragraph 52 that in your view "The statements of consumers, particularly those...in litigation, regarding their retrospective valuation of at-issue VCDs may not be